

## COMMITTEE REPORT

### MR. PRESIDENT:

The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 228, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

- 1       Page 1, between lines 12 and 13, begin a new paragraph and insert:
- 2       "SECTION 3. IC 12-7-2-190.6 IS ADDED TO THE INDIANA
- 3       CODE AS A NEW SECTION TO READ AS FOLLOWS
- 4       [EFFECTIVE UPON PASSAGE]: Sec. 190.6. "Therapeutic
- 5       classification" or "therapeutic category", for purposes of
- 6       IC 12-15-35, has the meaning set forth in IC 12-15-35-17.5.
- 7       SECTION 4. IC 12-15-35-17.5 IS ADDED TO THE INDIANA
- 8       CODE AS A NEW SECTION TO READ AS FOLLOWS
- 9       [EFFECTIVE UPON PASSAGE]: Sec. 17.5. As used in this chapter,
- 10      "therapeutic classification" or "therapeutic category" means a
- 11      group of pharmacologic agents primarily characterized by a
- 12      significant similarity of the biochemical or physiological
- 13      mechanism by which these agents result in the intended clinical
- 14      outcome.
- 15      SECTION 5. IC 12-15-35-20.1, AS ADDED BY P.L.231-1999,
- 16      SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
- 17      UPON PASSAGE]: Sec. 20.1. (a) Each board member **and each**
- 18      **therapeutics committee member** shall fully disclose any potential
- 19      conflicts of interest, financial or otherwise, relating to an issue that
- 20      comes before the board **or committee** for recommendation or other

1 action.

2 (b) A board member **or therapeutics committee member** may not  
3 vote on a recommendation or other action if the member or the  
4 member's employer has a conflict of interest, financial or otherwise, in  
5 the outcome of the vote.

6 (c) A board member **or therapeutics committee member** who may  
7 not vote on a recommendation or other action under subsection (b) may  
8 still participate in any discussions regarding the recommendation or  
9 other action.

10 SECTION 6. IC 12-15-35-20.5 IS ADDED TO THE INDIANA  
11 CODE AS A NEW SECTION TO READ AS FOLLOWS  
12 [EFFECTIVE UPON PASSAGE]: **Sec. 20.5. (a) The therapeutics**  
13 **committee is established as a subcommittee of the board.**

14 (b) **The chairperson of the board elected under section 25 of this**  
15 **chapter shall, with the approval of a majority of a quorum of the**  
16 **board, appoint the members of the therapeutics committee.**

17 (c) **The therapeutics committee is composed of the following**  
18 **members:**

- 19 (1) **Six (6) physicians licensed under IC 25-22.5, including:**  
20 (A) **one (1) physician with expertise in the area of**  
21 **infectious diseases;**  
22 (B) **one (1) physician with expertise in the area of**  
23 **pediatrics;**  
24 (C) **one (1) physician with expertise in the area of**  
25 **geriatrics;**  
26 (D) **one (1) physician with expertise in psychiatric**  
27 **medicine;**  
28 (E) **one (1) physician with expertise in the area of internal**  
29 **medicine and who specializes in the treatment of diabetes;**  
30 **and**  
31 (F) **one (1) physician with expertise in the area of**  
32 **cardiovascular medicine.**  
33 (2) **Five (5) pharmacists licensed under IC 25-26, including:**  
34 (A) **one (1) pharmacist who has experience in pharmacy**  
35 **benefit management and is employed by a health**  
36 **maintenance organization that has a pharmacy benefit;**  
37 (B) **one (1) pharmacist who is employed or has been**  
38 **employed by a hospital pharmacy or a retail pharmacy;**

- 1 (C) one (1) pharmacist who is employed or has been  
2 employed in the area of long term care pharmacy;
- 3 (D) two (2) pharmacists who have a doctor of pharmacy  
4 degree or an equivalent degree and who have either:  
5 (i) completed a residency in drug information; or  
6 (ii) had at least three (3) years of recent experience in  
7 prescription drug formulary management, including  
8 therapeutic category review.
- 9 (d) Not more than three (3) of the individuals appointed by the  
10 chairperson under subsection (b) to the therapeutics committee  
11 may also be members of the board.
- 12 (e) At least three (3) of the members described in subsection  
13 (c)(1) and appointed under subsection (b) must have at least three  
14 (3) years of recent experience in prescription drug formulary  
15 management, including therapeutic category review.
- 16 (f) A member of the therapeutics committee may not:  
17 (1) be employed by; or  
18 (2) contract with;  
19 a pharmaceutical manufacturer or labeler.
- 20 (g) The term of a member of the therapeutics committee is three  
21 (3) years. A member may be reappointed to the committee upon  
22 the completion of the member's term.
- 23 (h) The expenses of the therapeutics committee shall be paid by  
24 the office.
- 25 (i) Each member of the therapeutics committee who is not a  
26 state employee is entitled to the minimum salary per diem provided  
27 by IC 4-10-11-2.1(b). The member is also entitled to  
28 reimbursement for traveling expenses as provided under  
29 IC 4-13-1-4 and other expenses actually incurred in connection  
30 with the member's duties as provided in the state policies and  
31 procedures established by the Indiana department of  
32 administration and approved by the budget agency.
- 33 (j) Each member of the therapeutics committee who is a state  
34 employee is entitled to reimbursement for traveling expenses as  
35 provided under IC 4-13-1-4 and any other expenses actually  
36 incurred in connection with the member's duties as provided in the  
37 state policies and procedures established by the Indiana  
38 department of administration and approved by the budget agency.

1       **(k) The affirmative votes of a majority of the voting members**  
 2       **appointed to the therapeutics committee are required for the**  
 3       **committee to take action on any measure.**

4       SECTION 7. IC 12-15-35-26, AS AMENDED BY P.L.291-2001,  
 5       SECTION 162, IS AMENDED TO READ AS FOLLOWS  
 6       [EFFECTIVE UPON PASSAGE]: Sec. 26. **(a)** The secretary shall  
 7       provide additional staff to the board.

8       **(b) The secretary shall provide staff for the therapeutics**  
 9       **committee.**

10       SECTION 8. IC 12-15-35-28 IS AMENDED TO READ AS  
 11       FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 28. **(a)** The board  
 12       has the following duties:

13       (1) The adoption of rules to carry out this chapter, in accordance  
 14       with the provisions of IC 4-22-2 and subject to any office  
 15       approval that is required by the federal Omnibus Budget  
 16       Reconciliation Act of 1990 under Public Law 101-508 and its  
 17       implementing regulations.

18       (2) The implementation of a Medicaid retrospective and  
 19       prospective DUR program as outlined in this chapter, including  
 20       the approval of software programs to be used by the pharmacist  
 21       for prospective DUR and recommendations concerning the  
 22       provisions of the contractual agreement between the state and any  
 23       other entity that will be processing and reviewing Medicaid drug  
 24       claims and profiles for the DUR program under this chapter.

25       (3) The development and application of the predetermined criteria  
 26       and standards for appropriate prescribing to be used in  
 27       retrospective and prospective DUR to ensure that such criteria  
 28       and standards for appropriate prescribing are based on the  
 29       compendia and developed with professional input with provisions  
 30       for timely revisions and assessments as necessary.

31       (4) The development, selection, application, and assessment of  
 32       interventions for physicians, pharmacists, and patients that are  
 33       educational and not punitive in nature.

34       (5) The publication of an annual report that must be subject to  
 35       public comment before issuance to the federal Department of  
 36       Health and Human Services and to the Indiana legislative council  
 37       by December 1 of each year.

38       (6) The development of a working agreement for the board to

clarify the areas of responsibility with related boards or agencies,  
including the following:

- (A) The Indiana board of pharmacy.
- (B) The medical licensing board of Indiana.
- (C) The SURS staff.
- (7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.
- (8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:
  - (A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.
  - (B) Potential or actual severe or adverse reactions to drugs.
  - (C) Therapeutic appropriateness.
  - (D) Overutilization or underutilization.
  - (E) Appropriate use of generic drugs.
  - (F) Therapeutic duplication.
  - (G) Drug-disease contraindications.
  - (H) Drug-drug interactions.
  - (I) Incorrect drug dosage and duration of drug treatment.
  - (J) Drug allergy interactions.
  - (K) Clinical abuse and misuse.
- (9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.
- (10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.
- (11) The research, development, and approval of a preferred drug list for Medicaid's fee for service program and primary care case management program in consultation with the therapeutics committee.**

1           **(12) The approval of the review and maintenance of the**  
 2           **preferred drug list at least two (2) times per year.**

3           **(13) The review of the committee's recommendations**  
 4           **concerning a new prescription drug that has recently entered**  
 5           **the market in order to determine whether the drug should be**  
 6           **included on the preferred drug list.**

7           **(b) The board shall use the clinical expertise of the therapeutics**  
 8           **committee in developing a preferred drug list.**

9           **(c) In researching and developing a preferred drug list under**  
 10          **subsection (a)(11), the board shall do the following:**

11           **(1) Use literature abstracting technology.**

12           **(2) Use commonly accepted guidance principles of disease**  
 13           **management.**

14           **(3) Develop therapeutic classifications for the preferred drug**  
 15           **list.**

16           **(4) Give substantial consideration to the clinical efficacy or**  
 17           **appropriateness of a particular drug in treating a specific**  
 18           **medical condition.**

19           **(5) Include in any cost effectiveness considerations the cost**  
 20           **implications of other components of the state's Medicaid**  
 21           **program.**

22          **(d) A practitioner who is authorized to prescribe medication**  
 23          **under IC 25 may prescribe a drug that is not on the preferred drug**  
 24          **list if the practitioner receives prior authorization.**

25          SECTION 9. IC 12-15-35-28.5 IS ADDED TO THE INDIANA  
 26          CODE AS A NEW SECTION TO READ AS FOLLOWS  
 27          [EFFECTIVE UPON PASSAGE]: **Sec. 28.5. The therapeutics**  
 28          **committee established under section 20.5 of this chapter shall do**  
 29          **the following:**

30           **(1) Advise and make recommendations to the board in the**  
 31           **board's development and maintenance of a preferred drug list**  
 32           **under section 28 of this chapter.**

33           **(2) Submit to the board a proposed preferred drug list that**  
 34           **has been approved by a majority of the voting members of the**  
 35           **therapeutics committee.**

36           **(3) Advise and make recommendations to the board in the**  
 37           **board's annual review and maintenance of a preferred drug**  
 38           **list.**

SECTION 10. IC 12-15-35-28.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.7. (a) The board shall submit the approved preferred drug list to the office not later than August 1, 2002.**

**(b) The office may implement the preferred drug list developed and approved by the board under section 28 of this chapter after June 30, 2002. However, the office shall implement this list not later than September 1, 2002.**

**(c) The office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.**

**(d) The office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.**

**(e) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter."**

Page 5, between lines 16 and 17, begin a new paragraph and insert:

"SECTION 14. IC 25-1-9-6.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 6.8. (a) This section applies to a practitioner who is:**

- (1) licensed to practice medicine or osteopathic medicine under IC 25-22.5;**
- (2) licensed as an advanced practice nurse under IC 25-23; or**
- (3) certified as a physician assistant under IC 25-27.5.**

**(b) Before prescribing a psychotropic medication for a child for the treatment of attention deficit hyperactivity disorder, a practitioner described in subsection (a) shall:**

- (1) follow the most recent guidelines adopted by the American Academy of Pediatrics for the diagnosis and evaluation of a child with attention deficit hyperactivity disorder; and**
- (2) obtain, if the child:**
  - (A) is a recipient of Medicaid under IC 12-15 or the children's health insurance program under IC 12-17.6, prior authorization; or**
  - (B) is not described in clause (A), an opinion from another practitioner who is licensed under IC 25-22.5 that**

1 treatment with a psychotropic medication is appropriate  
2 for the child.

3 (c) In addition to the actions listed under section 4 of this  
4 chapter that subject a practitioner to the exercise of disciplinary  
5 sanctions, a practitioner described in subsection (a) is subject to the  
6 exercise of disciplinary sanctions under section 9 of this chapter if,  
7 after a hearing, the board regulating the practitioner's profession  
8 finds that the practitioner has violated subsection (b).

9 SECTION 15. [EFFECTIVE UPON PASSAGE] The chairperson  
10 shall make the appointments required under IC 12-15-35-20.5, as  
11 added by this act, not more than thirty (30) days after the effective  
12 date of this act.

13 SECTION 16. [EFFECTIVE UPON PASSAGE] Upon the effective  
14 date of this act, any drug that is included on the preferred drug list  
15 implemented by the drug utilization review board under  
16 IC 12-15-35-28, as amended by this act, may not require prior  
17 authorization.

18 SECTION 17. [EFFECTIVE UPON PASSAGE] (a) As used in this  
19 SECTION, "committee" refers to the therapeutics committee  
20 established by IC 12-15-35-20.5, as added by this act.

21 (b) The initial terms of office for the members of the committee  
22 are as follows:

23 (1) Of the members appointed under IC 12-15-35-20.5(c)(1),  
24 as added by this act:

25 (A) two (2) members shall be appointed for a term of one

26 (1) year;

27 (B) two (2) members shall be appointed for a term of two

28 (2) years; and

29 (C) two (2) members shall be appointed for a term of three

30 (3) years.

31 (2) Of the members appointed under IC 12-15-35-20.5(c)(2),  
32 as added by this act:

33 (A) one (1) member shall be appointed for a term of one (1)  
34 year;

35 (B) two (2) members shall be appointed for a term of two

36 (2) years; and

37 (C) two (2) members shall be appointed for a term of two

38 (2) years.



- 1        **(c) This SECTION expires December 31, 2003."**
- 2        Renumber all SECTIONS consecutively.  
      (Reference is to SB 228 as introduced.)

**and when so amended that said bill do pass.**

Committee Vote: Yeas 10, Nays 0.

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**Miller**

**Chairperson**